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## **U.S. REACHES \$124 MILLION SETTLEMENT WITH DRUG MAKER**

### **Manufacturer Allegedly Overcharged Federal And State Governments – U.S. To Recover \$73 Million, Participating States \$51 Million**

PHILADELPHIA – Patrick L. Meehan, United States Attorney for the Eastern District of Pennsylvania, announced today that King Pharmaceuticals, Inc., and its subsidiary Monarch Pharmaceuticals, Inc., have agreed to pay approximately \$124 million to resolve civil fraud liabilities under the federal False Claims Act and other federal and state statutes and common law principles.

King Pharmaceuticals, located in Bristol, Tennessee, underpaid rebates for its pharmaceutical products owed to the United States and the states participating in the Medicaid Rebate Program from 1994 through 2002. King also overcharged the Department of Veterans Affairs, the federal Public Health Services entities, and certain state governmental entities for its pharmaceutical products. King's principal drug involved in the settlement is Altace, an ACE (Angiotensin Converting Enzyme) inhibitor that reduces the likelihood of heart attack and stroke. The purpose of the Medicaid Rebate Program is to ensure that Medicaid receives the benefit of the lowest price available in the marketplace for Medicaid reimbursed drugs.

"Taxpayers fund the Medicaid Rebate Program through their payroll deductions," said Meehan. "When the government is overcharged, it affects all of us. Settlements like this should convince manufacturers that their drug price reporting to Medicaid must be accurate and complete. They must understand that overcharging government customers for drugs has an impact on every taxpayer."

Once it became aware of the allegations against it, King conducted an extensive investigation of its pricing practices. King retained a major accounting firm to review each drug sale, and it completely recalculated its drug prices for the eight-year period from 1994 to 2002. King cooperated extensively with the United States' investigation and brought forward much of the information on which the settlement is based.

The civil settlement resolves claims that (1) King knowingly failed to report accurately to the Center of Medicare and Medicaid Services on a quarterly basis the Average Manufacturer Prices and Best Prices for certain of its drug products and to pay the corresponding proper amounts of Medicaid rebates, (2) King overcharged Public Health Service entities for certain of its drug products, and (3) King failed to provide accurate information to the Department of Veterans Affairs and overcharged for drug products purchased by users of the Federal Supply Schedule.

"As this case demonstrates, the federal government will continue its vigilance over and enforcement of the Medicaid drug rebate program," said Daniel R. Levinson, Inspector General of the Department of Health and Human Services. "Pharmaceutical companies need robust compliance programs that include clear procedures for calculating drug prices."

The HHS Office of Inspector General (HHS OIG) and King have entered into a Corporate Integrity Agreement. Among other things, the Agreement requires King to establish systems and policies designed to ensure that King accurately calculates and reports its Average Manufacturer Prices and Best Price figures in the future. The Settlement Agreement, which includes the Corporate Integrity Agreement, can be found at <http://www.usdoj.gov/usao/pae/News/Pr/2005/oct/oct05.html>

The United States' investigation and civil settlement encompasses allegations brought by a former employee of King. Edward Bogart, formerly Director of Contracts and National Accounts for King, filed an action on behalf of the United States under the *qui tam* provisions of the False Claims Act. Mr. Bogart also brought pendent state claims under the false claims statutes of thirteen states and the District of Columbia. The United States and Mr. Bogart have not reached agreement on a share of the proceeds of the settlement.

The Department of Health and Human Services Office of Inspector General, the Department of Veterans Affairs, and a team assembled by the National Association of Medicaid Fraud Control Units (NAMFCU) participated in this investigation, which was conducted jointly by the United States Attorney's Office and the Fraud Section of the Civil Division.

"This settlement shows that the compliance efforts that the federal government and the pharmaceutical companies have in place can help protect the Medicaid beneficiaries and taxpayers," said CMS Administrator Mark B. McClellan, M.D., Ph.D. "With Medicare prescription drug coverage beginning in January, we are being especially watchful about our payments for prescription drugs."

Today's settlement is part of an ongoing effort by the U.S. Attorney's Office in the Eastern District of Pennsylvania to ensure that drug manufacturers, under the provisions of the Medicaid Rebate Statute, provide drugs to Medicaid at the best price that they charge commercial customers. In July 2004, Schering-Plough Corporation agreed to pay more than \$290 million to resolve its civil liabilities in connection with its illegal and fraudulent pricing of its blockbuster drug, Claritin. Schering Sales Corp., a subsidiary of Schering-Plough, agreed to plead guilty to criminal charges and pay a fine of \$52.5 million.

Assistant United States Attorney Barbara Rowland and Department of Justice Trial Attorney Sanjay M. Bhambhani handled the civil investigation. Senior Counsel Mary E. Riordan in the Office of Counsel to HHS OIG negotiated the Corporate Integrity Agreement.

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